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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,612	10/23/2001	Hugo Cesar Gramajo	0380-P02327US1	1004
110	7590	10/03/2003	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/045,612

Applicant(s)

GRAMAJO ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. Claims 1-51 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-20, drawn to nucleic acids encoding an AccB polypeptide, vectors thereof and host cells thereof, classified in class 435, subclass 252.35.
 - II. Claims 21-28, drawn to methods of producing a polyketide, classified in class 435, subclass 76.
 - III. Claims 29-38 and 42-46, drawn to methods of modifying a *Streptomyces* strain and the resulting product, classified in class 435, subclass 471.
 - IV. Claims 39-41, drawn to methods of producing a polyketide using a *Streptomyces* strain with increased expression of AccB, classified in class 435, subclass 76.
 - V. Claims 47-51, drawn to methods making a polyketide using exogenous malonate in the culture, classified in class 435, subclass 76.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case, the host cells can be used for a materially different process of using the product, such as in the recombinant production of AccB polypeptides for purification. Thus, Groups I and II are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to Groups III and IV because the nucleic acids of Group I must be overexpressed in the methods of Groups III and IV. However, the methods of Groups III and IV neither require the use of nor make the nucleic acids of Group I because a promoter can be inserted into the genome upstream of the endogenous AccB gene and meet all the limitations of Group III-IV methods. Thus, Group I is patentably distinct from Groups III and IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups I and V are related because overexpression of the AccB gene of Group I has the same effect as adding exogenous malonate as prescribed by the methods of Group V. However, the products of Group I are neither used nor made in the methods of Group V. Thus, these Groups are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups II and III are related by overexpression of the AccB gene. However, distinct means for overexpression can be used in the methods as noted above. Thus, the methods steps can be distinct rendering the Groups distinct. Thus, Groups II and III are

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patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups II, IV, and V are all related as methods of making polyketides. However, these methods are distinct because they require the use of distinct method steps using a particular nucleic acid, overexpression of a particular nucleic acid, or adding of an exogenous compound naturally made from the protein product of the nucleic acid. Thus, Groups II, IV and V are patentably distinct, each from the other. Because these inventions are distinct for the reasons given above and the searches required for Groups II, IV, and V are not co-extensive, restriction for examination purposes as indicated is proper. Particularly, the Examiner notes that the AccB nucleic acid is required in Group II, any means of increased expression of the AccB nucleic acid is required in Group IV, and only exogenous malonate is required in Group V.

Groups III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products can be used for a materially different process of using the product, such as in the recombinant expression of AccB polypeptides for purification. Thus, Groups III and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Groups III and V are related because the cells overexpressing AccB in Group III have the same effect in a method of producing polyketides as does adding exogenous malonate as found in Group V. However, the products of Group III are neither used nor made in the methods of Group V. Thus, these Groups are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims in Group I or III are found directed to an allowable product, then process claims in Group II or IV, respectively, which are directed to processes of making or using the patentable product, respectively, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re Ochiai*, and *In re Brouwer*). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

5. A telephone call was made to Patrick Hagan on September 26, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

September 26, 2003

